

July 5, 2005

Docket No. 05-015-1  
Regulatory Analysis and Development  
PPD, APHIS, Station 3C71  
4700 River Road Unit 118  
Riverdale, MD 20737-1238

Re: Docket No. 05-015-1, *National Animal Identification System; Notice of Availability of a Draft Strategic Plan and Draft Program Standards*, *Federal Register*, May 6, 2005, p.23962.

Dear Sir or Madam:

The following comments are submitted by the National Dairy Herd Improvement Association (DHIA), to the Animal and Plant Health Inspection Service (APHIS) in response to the *National Animal Identification System; Notice of Availability of a Draft Strategic Plan and Draft Program Standards* [Docket No. 05-015-1]. National DHIA which represents over 27,000 dairy operations including over 50,000 producers, with 4.2 million producing cows in all regions of the nation, strongly supports the rapid implementation of the National Animal Identification System (NAIS). We believe that it will be a vital tool for protecting the health of our livestock and the economic well-being of producers.

Our organization was actively involved in development of the United States Animal Identification Plan (USAIP), which provided the basic structure for the NAIS. We are currently working with other partners through the Cattle Species Work Group, the Dairy Subcommittee and various pilot projects, to begin implementation the NAIS. National DHIA has pushed repeatedly for clarification of key elements that are needed to begin the implementation of the NAIS. We appreciate the publication of these documents as an indication of current APHIS thinking in these areas. It is another important step toward implementation of the system and we welcome the opportunity to respond to the questions included in the notice and to provide comments on the two documents.

The following comments are provided for USDA use, in response to the specific questions posed by APHIS in the Notice of Availability:

- The Draft Strategic Plan calls for making the entire system mandatory by January 2009. Is a mandatory identification program necessary to achieve a successful animal disease surveillance, monitoring, and response system to support Federal animal health programs? Please explain why or why not.

National DHIA firmly believes that a mandatory system is necessary if we are to meet the stated objective of identifying all animals and premises that had direct contact with a foreign animal disease (FAD) or disease of concern within 48 hours of discovery of that disease. Unidentified animals are at equal risk of becoming infected during a disease outbreak, but the presence of unidentified animals or

premises would make it much more difficult to complete the needed traces. This would negate much of the value of the investment that all owners of identified animals, as well as state and federal governments, have made in the system. All animals would remain at potential risk.

- In the current Draft Strategic Plan, the NAIS would require that producers be responsible for having their animals identified before the animals move to a premises where they are to be commingled with other animals, such as a sale barn. At what point and how should compliance be ensured? For example, should market managers, fair managers, etc., be responsible for ensuring compliance with this requirement before animals are unloaded at their facility or event? Please give the reasons for your response.

National DHIA believes that it is the producer's responsibility to assure that their animals are properly identified prior to being commingled. Managers of markets, fairs, etc. need to verify the identification of animals arriving at their facility as a normal function of their operation. Current procedures may be somewhat different than what will be needed for the NAIS, but it would appear to be most efficient to work with these managers to make any needed adjustments to their processes or provide some basic enhancements of their infrastructure to allow them to serve as the initial point for verification of compliance. Having tagging services available at such facilities would provide a convenient way for producers to assure that they comply with NAIS requirements.

- In regard to cattle, individual identification would be achieved with an AIN tag that would be attached to the animal's left ear. It is acknowledged that some producers do not have the facilities to tag their animals; thus, the Draft Program Standards document contains an option for tagging sites, which are authorized premises where owners or persons responsible for cattle could have the cattle sent to have AIN tags applied. Do you think this is a viable option, i.e., can markets or other locations successfully provide this service to producers who are unable to tag their cattle at their farms? Please give the reasons for your response.

National DHIA anticipates that a variety of tagging options, such as tagging sites, tagging services, etc. will need to be available to producers, at least initially in order to achieve full compliance. While it seems unlikely that many producers would choose to move animals to a tagging site strictly for tagging, having this service available at markets, fairs, or other locations where animals move prior to commingling, would appear to be a useful service and is likely to increase acceptance of the system by producers. It is important that there be strong oversight of these services to assure that they do comply with NAIS standards. It would be useful to have one or more pilot projects evaluate the feasibility of such options.

- The current Draft Strategic Plan does not specify how compliance with identification and movement reporting requirements will be achieved when the sale is direct

between a buyer and seller (or through their agents). In what manner should compliance with these requirements be achieved? Who should be responsible for meeting these requirements? How can these types of transactions be inputted into the NAIS to obtain the necessary information in the least costly, most efficient manner?

It is the understanding of National DHIA that in the NAIS the buyer has the basic responsibility for reporting these transactions. This is appropriate; however, sellers also have a vested interest in reporting when animals have been removed from their premise. The draft Program Standards includes an “Animal Event Code” for “Moved out – Animal is moved out of a premises” and a field for reporting the “Destination Premises” in the Individual Animal Data Elements format for the National Animal Records Repository that provide a means for the seller to also report the movement. Encouraging event reporting by both parties in the transaction will enhance the probability of having needed data reported and provide a secondary verification of animal movement. Providing multiple ways in which the information may be reported should allow producers to find the most cost effective way to report the information. Service providers such as the DHIA and other value added data handlers will be well positioned to submit these transaction records for members/clients since they would be doing it as a routine part of their business. Licensed dealers or agents should also be positioned to do this. Providing web based or telephone reporting options for producers may also be useful options. Gathering information on reporting options is another area that should be explored through pilot projects.

- USDA suggests that animals should be identified anytime prior to entering commerce or being commingled with animals from other premises. Is this recommendation adequate to achieve timely traceback capabilities to support animal health programs or should a timeframe (age limit) for identifying the animals be considered? Please give the reasons for your response.

Dairy animals are identified at birth as a routine management practice on most operations. ID is an important management practice and the time shortly after birth is the easiest time to work with the animal to apply the ID device. Thus, we anticipate that RFID tags will be viewed as important management tools for producers and most dairy animals will be identified shortly after birth. This would appear to be the ideal time for all animals to be identified; however, as long as there is strong oversight to assure that animals are identified before leaving their birth premise, the traceback ability of the system should be adequate for animal health programs and for meeting the objectives of NAIS.

- Are the timelines for implementing the NAIS, as discussed in the Draft Strategic Plan, realistic, too aggressive (i.e., allow too little time), or not aggressive enough (i.e., do not ensure that the NAIS will be implemented in a timely manner)? Please give the reasons for your response.

National DHIA believes that sooner is better than later and strongly support beginning to report information to the system as soon as possible so that needed

databases and data reporting systems can begin to function and be well tested prior to the system becoming mandatory. However, given the challenges of integrating data capture technology into our existing infrastructure and implementing mandatory reporting, the timelines appear realistic. Therefore, National DHIA supports strict adherence to the Strategic Plan timelines of January 2008 for premise registration and animal identification with enforcement and January 2009 for mandatory implementation of all aspects of the program.

- Should requirements for all species be implemented within the same timelines, or should some flexibility be allowed? Please give the reasons for your response.

Many diseases of concern and the vectors that harbor or spread those diseases are multi-species in nature, thus the NAIS will not be fully functional until all species are included. For this reason, National DHIA believes that the timeline for implementation for all species should be consistent.

- What are the most cost-effective and efficient ways for submitting information to the database (entered via the Internet, file transfer from a herd-management computer system, mail, phone, third-party submission of data)? Does the type of entity (e.g., producer, market, slaughterhouse), the size of the entity, or other factors make some methods for information submission more or less practical, costly, or efficient? Please provide supporting information if possible.

Multiple platforms must be available for data entry. Any of the above mentioned systems could work. The DHIA system (a third party, herd-management computer system) provides a familiar, easy to use system for the majority of dairy producers and the reporting functions could easily be made available to other species as well. However, even within the DHIA system different options are desirable. In some cases it will be most effective and efficient to transfer information directly from an on-farm system to the NAIS. In other cases it may be transferred from an intermediate platform between the farm and the Dairy Records Processing Center (DRPC) where large databases are maintained and in other cases delivery of data to the system by the DRPC will be the most effective method. If a variety of reasonable options are available producers and other participants will be able to find the method that works best for their situation. The electronic capture and transfer of data needed in the system should minimize reporting errors, but especially as the system begins, it will be important for reporting choices to be available. Once again, pilot projects offer an excellent vehicle for assessing the efficiency, effectiveness and acceptability of the various potential options.

- We are aware that many producers are concerned about the confidentiality of the information collected in the NAIS. Given the information identified in the draft documents, what specific information do you believe should be protected from disclosure and why?

In general, dairy producers have not had the same level of concern over confidentiality as shown by some other species. Dairy producers recognize that much of the information is already available from other sources and the industry has routinely supplied information to a national database use in genetic evaluation of animals for many years with few problems. That said we do support protecting the confidentiality of all data to the extent possible. Information in the Premises Repository appears to be the most sensitive, since it provides specific location information for each premise where animal are kept or potentially commingled. We do note that the description of the national animal movement repository on page 2 identifies four pieces of information that would be maintained in the repository to facilitate tracking. This is appropriate and we support that concept. The format on page 12 includes several additional pieces of information. It is unclear if the other items are optional or required as well as when and how this information is expected to be collected. This apparent discrepancy should be addressed. We do have concerns about “information drift.” The national repository needs to focus on having the data required to efficiently and effectively conduct needed traces in an animal health emergency.

- The NAIS as planned would require States, producers, and other participating entities to provide information and develop and maintain records. How could we best minimize the burden associated with these requirements? For example, should both the seller and the buyer of a specific group of animals report the movement of the animals, or is reporting by one party adequate?

National DHIA and the dairy industry have strongly advocated the use of existing systems to capture, store and report the needed information to the NAIS. Using existing systems, that have demonstrated that they are compatible with the NAIS will be most cost effective, should minimize reporting errors and should eliminate any need for duplicate record systems or reporting by producers. Producers will be much more receptive to the NAIS if it will work with their existing records systems. We mentioned earlier the desirability of movement reporting by both buyer and seller. We do not believe that reporting by both parties needs to be mandated, but rather should be encouraged. If existing systems are used to capture and report animal movements this level of dual reporting and validation of movement can be accomplished with very minimal additional cost or effort for any of the parties involved.

The Notice indicated that “a key issue in the development of the NAIS concerns the management of animal tracking information. Animal health officials must have immediate, reliable, and uninterrupted access to essential NAIS information for routine surveillance activities and in the event of a disease outbreak. APHIS determined that this goal could best be achieved by having the data repositories managed by APHIS. The Draft Program Standards document provides for two main NAIS information repositories: The National Premises Information Repository and the National Animal Records Repository. The National Premises Information Repository would maintain data on each production and animal

holding location (contact name, address, phone number, type of operation, etc.). The National Animal Records Repository would maintain animal identification and movement data.

Recently, however, an industry-led initiative suggested a privately managed database as an alternative for the management of data on animal tracking in the NAIS. The industry group stated that a private database would ensure that the needs of both government and industry would be fulfilled, and that the flow of information throughout the NAIS would be maintained in a secure and confidential manner. APHIS is requesting comment from stakeholders regarding the utility of a privately managed database for holding animal location and movement information.” The following are our comments on the specific questions related to this issue:

- How should a private database system be funded? Please give the reasons for your response.

National DHIA strongly supports the concept of a national database under the management of APHIS as defined in the draft Program Standards. We indicated previously the need for a mandatory system. A mandatory system does not appear consistent with the concept of with a private database. We also believe that a public database is the most effective way to assure 24/7 access to information needed by state and federal animal health officials to prepare for and address animal health emergencies. In addition this should be the most cost effective system for producers. The national repository serves a “common good” for the entire nation and as such should be publicly funded rather than privately funded as a private database would need to be. Private databases, that offer value added opportunities for producers and that are funded by their users, should be encouraged to be a part of the system, but not to function as the total system. They can be the most efficient, cost effective method to capture and input data required by the national repository, but they are not as well suited to function as the national repository. Differences within and between species would make it difficult, if not impossible for a private database to function in the role outlined for the national repository.

- Should the NAIS allow for multiple privately managed databases? Please explain why or why not.

Multiple privately managed databases can be a valuable resource for the NAIS as a way to efficiently capture and report information to a national repository. They allow producers and other participants to use the system that best fits their operational needs. However, as indicated previously they are not an adequate replacement for a single national repository under the management of APHIS.

- Should a public (government) system be made available as well as a privately managed system so that producers would have a choice? Please give the reasons for your response.

We believe that the system will be most effective if privately managed systems supply the minimal information needed by the NAIS to a public system under the management of APHIS. This will maximize the use of existing resources and minimize reporting burdens for producers. However, the option of providing information directly to the public system will need to be available as not all producers are likely to work with a private service provider.

- Should a privately managed system include all species? Please give the reasons for your response.

In order to meet the objective of the NAIS, of identifying all animals and premises that had direct contact with a foreign animal disease (FAD) or disease of concern within 48 hours of discovery of that disease, it is critical that information on all species be available. Many diseases are expressed in multiple species and people, vehicles and other vectors move between facilities with different species, thus the need for immediate access to information from all species. This concept is included in the APHIS managed public database described in the draft Program Standards. It would be much more difficult to achieve with a private system, thus a compelling reason to have the public national repository.

- Would either system work equally well at the State level? Please explain why or why not.

A state database has the same basic needs and faces many of the same challenges as the national system. State animal health officials have initial responsibility in most disease outbreaks, so it is critical that they have immediate access to all data in their state. It is also crucial that there be almost immediate data sharing across the state and national systems to assure that each has the most current animal location/movement information. It appears that this can best be accomplished with state databases that are under the management of the state animal health officials. States may choose to contract with private vendors to operate their database, but they need to be under the immediate control of the state animal health official.

We trust that the above responses will be useful to APHIS as planning for the system moves forward. While the questions address a range of issues and options, we would like to offer several additional comments related to the specific documents.

National DHIA supports the basic concepts included in the Draft Strategic Plan, including data repositories for tracking animal movement that are managed by APHIS to allow 24/7 access to data required to track movement and a time specific for making the system mandatory. As noted in our response to the questions, we believe this is necessary if the goals of NAIS are to be met. We do appreciate and agree with the recognition on page 2 the “Much of the responsibility for delivering the program remains at the state level.” Page 14 highlights the importance of cooperation by all parties to the overall success of the effort. It is important to keep these two factors in mind as the system evolves, for the enthusiastic involvement of states and other cooperators will be necessary for the NAIS to succeed.

Page 2 includes a heading of **Input, outreach and training**, but there is limited additional mention of the outreach and training component. A much stronger outreach component than has been shown to date will be important to the success of the effort during the voluntary stage and will be critical in laying the groundwork for a smooth transition to the mandatory aspect of the system. National DHIA has expressed concerns relative to the Governance of the effort since its inception. We do have concerns relative to input to the system at the present time. Page 5 indicates that a Subcommittee of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases has been established to make regular, formal recommendations to the Secretary's Advisory Committee as to how the NAIS should progress. National DHIA is positioned to provide input to the subcommittee, but we do have concerns related to this method of operation. First, how does the input to the Subcommittee actually get to and impact the NAIS? The Subcommittee reports to the Secretary's Advisory Committee who reports to the Secretary. Is there a mechanism for the input to get to the NAIS and get there in a timely manner? It is our understanding that the Secretaries Advisory Committee meets two times per year to provide input to the Secretary on a wide range of topics. What priority does the input from the Subcommittee have and is there a process for it to flow directly to those working with NAIS, or must it pass through several "filters" prior to being received by NAIS? A related concern is that there have been no official reports authorized to be released from the Subcommittee to industry detailing action on the input that has been provided. This is not a reflection on the members of the Subcommittee, but rather of the restrictions that the Subcommittee currently operates under. Industry input has been provided, but to date it is impossible to see if it has been received by and acted on by the leadership of the NAIS. Allowing the publication of meeting and action summaries from the Subcommittee will build awareness of and support for the process. If this is impossible, other more transparent forms of Governance should be explored.

Page 8 speaks of collaboration with market operators, dealers and service providers in field trials to implement data collection systems needed to collect animal movement records. National DHIA agrees that this is extremely important and encourages a focus on this in the next round of cooperative agreements. Virtually every state has a premise registration system available to producers. Now we need the infrastructure to collect and report the movement data. It is critical that knowledge gained in these projects be rapidly shared with other states and tribes so they can avoid the pitfalls that have been identified and build on successes that are found.

Page 12 highlights the importance and anticipated difficulty in collecting animal movement information. Markets will be a key component of this effort. In order for them to cooperate effectively we believe that it is vital that a common technology be used from the start. For cattle, that is RFID tags that utilize the Animal Identification Number (AIN) as outlined in the plan. Markets need to be able to focus on capturing data from one technology and RFID is the only technology that appears to be able to function at the "speed of commerce" at the present time. Again, focusing new cooperative agreements and pilot project on efforts to develop systems that will work most effectively need to be pursued.



National DHIA supports the plans outlined on page 14 for APHIS management of data repositories with the limited number of pieces of data that they will require to conduct the traces that the NAIS is intended to facilitate. We also support the close integration and sharing of data between the national repository and those maintained by states or tribes. Confidentiality is important, but with the limited amount of data that will be stored, having the data immediately available to the appropriate animal health officials is even more critical to protect the well-being of our herds. We must note that the proposed data format included in Table 6 of the Draft Program Standards document is broader than what is indicated in the text, so this apparent difference needs to be resolved.

Page 16 indicates that the “840” numbers will be initiated in August 2005 with AIN tag manufacturers and AIN Managers. We are supportive of this timeline and expect to function in the role of AIN Manager; however, it is still unclear the process that will be required to be certified as either an AIN Tag manufacturer or a manager.

Pages 18 through 20 define stages of progress that will be used to implement progress. As pointed out in the plan the concept has been used numerous times in the past. The challenge with this appears to be that the denominator for several of the measures in stages II through V are largely unknown at the present time. How do you assure that states are in fact meeting the required percentages if these values are unknown? We also question point two for Stage III that indicate that states will begin to identify Non-producer participants in their state who may qualify as AIN managers. Is this a defined role in the process that states should perform and be judged upon?

Overall National DHIA believes that the Draft Strategic Plan identifies an appropriate plan of action and timeline for accomplishing it. We do believe that additional clarity is needed in those areas identified.

We are pleased that the Draft Program Standards maintain the basic direction defined in the USAIP. While there are several additions and modifications, the basic direction developed by the broad cross section of the animal industry that has been involved in the process from the start has been maintained. However, there are several items that we do wish to offer specific comments on.

Page 2 indicates that there are four pieces of information that will be collected and maintained in the National Animal Records Repository (NARR) that will provide the information needed to achieve 48 hour traceback. Page 12 indicates that the 17 data fields identified in table 6 will be maintained in the NARR with no indication as to which if any may be optional. Four of these fields are related to Alternative Animal ID, but this still means that more information may be maintained in the NARR than was indicated on page 2 with no provisions as to how it will be collected. This apparent discrepancy should be addressed.

Page 6 discusses **Official Identification Devices and Methods**. To effectively capture animal movement data, National DHIA believes that a common technology is essential so that all cooperating parties can be equipped to capture the needed data. Markets and other

collection points are not likely to be able to afford multiple technologies. National DHIA fully supports the use of RFID tags with the “840” AIN’s as the technology that should be implemented for cattle. As noted previously, markets are likely to only have one data collection system in place, but many markets handle multiple species. If other species that are likely to share markets with cattle choose other technology, pilot projects need to be initiated to determine way to most effectively handle this situation.

Page 8 indicates that event(s) that would trigger State or Federal access to the data management system include “1. A confirmed positive test for List A diseases.” It is our assumption this is intended to refer to an OIE list. The OIE has changed their system and now has reportable diseases, but not varying “lists” of diseases. This trigger needs to be clarified.

Page 18 indicates that the “reporting of animal movements would be the sole responsibility of the receiving premises...” National DHIA believes that it is appropriate that this be the responsibility of the receiving party; however, we do note that Table 7 includes an event code “4. Moved out – Animal is moved out of a premise”. Sellers should be encouraged, but not required to report this information. It is in our member’s self-interest to report that an animal is no longer on their premises and it also provides the system with a secondary check to help verify animal movement.

**Market Operators** and **Abattoirs** will be critical for the collection of movement information. We believe that it will work most efficiently if they only need to deal with one system and that system will need to be capable of moving at their “speed of commerce.”

Later on that page **AIN Tag Manufacturers** and **AIN Tag Managers** are discussed. Basic responsibilities are outlined, but clarification is still needed on the process to identify who will be certified to fill these roles by APHIS. This issue needs to be addressed immediately in order to meet the August timeline for having “840” tags available for producers and the AIN Managers in place to provide the needed oversight of the system.

Pages 24 and 25 both refer to data being reported to either the NARR or the State/Tribe Animal Identification and tracking system and subsequently shared with the other database. It is important that the data be shared, so that both the state/tribe and National systems have complete data sets; however, it is important to define specific reporting steps that will minimize the likelihood of duplicate reporting of the information.

Performance Standards for RFID tags are identified in Table 35. While the standards appear appropriate, it is unclear if APHIS will be the reviewer of tags, or what entities might fill this role. This is another area that needs immediate resolution in order to meet the timeline of having “840” tags available by August 2005.

The State Status Designation on pages 29 to 31 can be a useful way to measure progress. As indicated in the text, the concept has been used numerous times in the past. As noted in our comments on the Strategic Plan, the challenge with this appears to be that the denominator for several of the measures in stages II through V are largely unknown at the

present time. How do you assure that states are in fact meeting the required percentages if these values are unknown? We again question point two for Stage III that indicates that states will begin to identify Non-producer participants in their state who may qualify as AIN managers. Is this a defined role in the process that states should perform and be judged upon?

National DHIA again appreciates the opportunity to review these documents that represent current USDA thinking relative to the implementation of the NAIS and to share our comments on them. We believe that both drafts reflect needed, positive movement by USDA. While we have offered suggested enhancements, we strongly encourage strict adherence to the timeline included in the Strategic Plan. It may be ambitious in some regards, but National DHIA supports rapid, full implementation of the system for all species. It is important for the protection of our national herd and the economic well-being of producers.

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